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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,308	02/09/2001	Luigi Naldini	40511	7081

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,308

Applicant(s)

NALDINI ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Claims 1-4 are pending in the instant application.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Sequences are disclosed in the specification that are not identified by their sequence identifier (i.e., SEQ ID NO:). For example, at page 16, lines 21-23, several primer sequences are disclosed, but none are identified by their sequence identifier. **Applicant is reminded that the entire specification and figures should be reviewed for sequence disclosures** and that each sequence disclosed in the specification must be identified by its sequence identifier (i.e., SEQ ID NO:). The specification must be amended to identify all disclosed sequences by their sequence identifier (i.e., SEQ ID NO), in accordance with 37 CFR 1.821(d). Since the specification discloses sequences that are not identified by their sequence identifier, it is unclear if all disclosed sequences are included in the sequence listing. A substitute CRF and paper copy of the Sequence Listing are required **only** if the unidentified sequences are not already included in the Sequence Listing.

Applicant is given the same shortened statutory period set forth for response to this Office Action within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these

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requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 4 are indefinite in their recitation of "said lentivirus" because the term has ambiguous antecedent basis. It is unclear to which lentivirus the claims are referring. Claim 1 recites both "a host infected with a lentivirus" and "a lentivirus vector." There is no requirement that the lentivirus vector be the same type of lentivirus that the host is infected with prior to administration of the vector.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 5,650,309 (Wong-Staal et al., issued July 22, 1997).

The claims are directed to a method for treating a host infected with a lentivirus by exposing the host to a lentivirus vector. No specific treatment effect is recited in the claims.

Wong-Staal et al. disclose an HIV-based vector useful for inhibiting viral replication in a cell. See Example 1, Columns 16-17. The HIV-LTR was shown to drive expression of the reporter construct (Column 16, lines 7-8). The vector disclosed qualifies as a lentiviral vector, as recited in the claims.

Claim 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,650,309 (Wong-Staal et al., filed May 16, 1995).

The claims are directed to a method for treating a host infected with a lentivirus by exposing the host to a lentivirus vector. No specific treatment effect is recited in the claims.

Wong-Staal et al. disclose an HIV-based vector useful for inhibiting viral replication in a cell. See Example 1, Columns 16-17. The HIV-LTR was shown to drive expression of the reporter construct (Column 16, lines 7-8). The vector disclosed qualifies as a lentiviral vector, as recited in the claims.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 5,665,577 (Sodroski et al., issued September 9, 1997).

The claims are directed to a method for treating a host infected with a lentivirus by exposing the host to a lentivirus vector. No specific treatment effect is recited in the claims.

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Sodroski et al. disclose an HIV-based vector useful for developing a vaccine for HIV. The HIV vector preferentially uses the HIV-1 LTR as the promoter. See Claim 10. The vector disclosed qualifies as a lentiviral vector, as recited in the claims.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,665,577 (Sodroski et al., filed February 6, 1989).

The claims are directed to a method for treating a host infected with a lentivirus by exposing the host to a lentivirus vector. No specific treatment effect is recited in the claims.

Sodroski et al. disclose an HIV-based vector useful for developing a vaccine for HIV. The HIV vector preferentially uses the HIV-1 LTR as the promoter. See Claim 10. The vector disclosed qualifies as a lentiviral vector, as recited in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irwin et al. (1994).

The claims are directed to a method for treating a host infected with a lentivirus by exposing the host to a lentivirus vector. No specific treatment effect is recited in the claims.

Irwin et al. (1994) disclose that direct injection of a lentiviral vector encoding HIV-1 proteins into mice and nonhuman primates produced an HIV-specific CTL immune response. Although the animals were not infected with HIV-1, the authors pointed out that the results of the studies demonstrate that the

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retrovector immunization method can be used to induce or augment CTL responses in HIV-1-infected individuals.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naldini et al. (1996) and Irwin et al. (1994).

The claims are directed to a method for treating a host infected with a lentivirus by exposing the host to a lentivirus vector. No specific treatment effect is recited in the claims.

Naldini et al. (1996) disclose that an HIV-derived retroviral vector was used to transduce nondividing cells. The vector contained an intact 5' LTR (see Figure 1). Naldini et al. does not describe the use of this vector in the treatment of a lentiviral-infected host.

Irwin et al. (1994) disclose that direct injection of a lentiviral vector encoding HIV-1 proteins into mice and nonhuman primates produced an HIV-specific CTL immune response. Although the animals were not infected with HIV-1, the authors pointed out that the results of the studies demonstrate that the retrovector immunization method can be used to induce or augment CTL responses in HIV-1-infected individuals.

Since one of skill in the art would have been motivated to provide a method for treating an HIV infection, the skilled artisan would have been motivated to combine the teachings of Naldini et al. and Irwin et al., wherein the HIV-derived vector of Naldini et al. was modified to encode HIV-1 proteins as demonstrated by Irwin et al. to thereby efficiently infect human cells and produce an HIV-specific CTL immune response in HIV-1-infected individuals.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

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Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER